

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
Assay Only Template**

A. 510(k) Number:

k101460

B. Purpose for Submission:

New Device

C. Measurand:

Calibrator materials for follicle stimulating hormone (FSH), luteinizing hormone (LH), prolactin (PRL) and estradiol (E2)

D. Type of Test:

Not Applicable

E. Applicant:

Siemens Healthcare Diagnostics Inc.

F. Proprietary and Established Names:

Dimension Vista® LOCI 8 Calibrator

G. Regulatory Information:

1. Regulation section:

21 CFR § 862.1150 - Calibrator

2. Classification:

Class II

3. Product code:

JIX

4. Panel:

75 (Chemistry)

H. Intended Use:

1. Intended use(s):

See indications for use, below.

2. Indication(s) for use:

The LOCI 8 CAL is an *in vitro* diagnostic product for the calibration of follicle stimulating hormone (FSH), luteinizing hormone (LH), prolactin (PRL) and estradiol (E2) methods on the Dimension Vista® Systems.

3. Special conditions for use statement(s):

For prescription use

4. Special instrument requirements:

For use with The Dimension Vista® 1000T, 500, 1500, and 3000T models

I. Device Description:

LOCI 8 CAL is a multi-analyte, liquid, frozen bovine serum albumin based product containing human follicle stimulating hormone, human luteinizing hormone, recombinant human prolactin, estradiol, buffers and preservatives. The calibrator packaging consists of ten vials with two vials per level containing 2.5 mL per vial.

The human blood products used in the manufacture of these calibrators has been tested using FDA approved methods and found to be non-reactive for HBsAg and antibodies to HCV and HIV-1/2.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Siemens Calibrator B (FSH, LH, Prolactin)
Roche Estradiol II CalSet II

2. Predicate 510(k) number(s):

k962041
k992981

3. Comparison with predicate:

Similarities		
Feature	New Device Dimension Vista® LOCI 8 CAL	Predicate Device Calibrator B (k962041)
Indications for Use	For calibration of the follicle stimulating hormone (FSH), luteinizing hormone (LH), and prolactin (PRL)	same
Constituents	FSH, LH, and Prolactin	same

Differences		
Feature	New Device Dimension Vista® LOCI 8 CAL	Predicate Device Calibrator B (k962041)
Form	Frozen liquid, bovine serum albumin	Lyophilized equine serum
Levels	5	2
Stability and storage	LOCI 8 CAL is stored at -25 to -15°C LOCI 8 CAL is stable, thawed and unopened for 7 days at 2-8°C	Calibrator B is stored at 2-8°C Calibrator B is stable, reconstituted for 28 days at 2-8°C

Similarities		
Feature	New Device Dimension Vista® LOCI 8 CAL	Predicate Device Estradiol II CalSet II (k992681)
Indications for Use	for calibration of a quantitative estradiol assay	same

Differences		
Feature	New Device - Dimension Vista® LOCI 8 CAL	Predicate Device Estradiol II CalSet II (k992681)
Constituents	Estradiol, FSH, LH and Prolactin	Estradiol
Form	Frozen liquid, bovine serum albumin	Lyophilized human serum
Levels	5	2
Stability and storage	LOCI 8 CAL is stored at -25 to -15°C. LOCI 8 CAL is stable, thawed and unopened for 7 days at 2-8°C.	Elecsys Estradiol II CalSet II is stored at 2-8°C. Elecsys Estradiol II CalSet II is stable, reconstituted three months when stored at -20°C if frozen only once.

K. Standard/Guidance Document Referenced (if applicable):

FDA Guidance for Industry - Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators; Final

L. Test Principle:

Not Applicable

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Not Applicable

b. *Linearity/assay reportable range:*

Not Applicable

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

Traceability:

For each analyte an anchor pool is prepared using a WHO standard material. The LOCI 8 Anchor Pool for each analyte is manufactured by spiking four levels of WHO standard, which span the assay range, into normal human serum previously screened for low levels of the analyte of interest. The zero calibrator for the anchor pool is bovine serum albumin calibrator base. A four level masterpool is prepared with bovine serum albumin and assigned values on the Dimension Vista® instrument system versus the anchor pool. The masterpools are stored at -70C and are used to assign commercial calibrator lots. The commercially available values for each analyte are as follows:

LOCI 8 Calibrator – Analyte Information			
Analyte	Method Assay Range	Reference	Assigned Values
Estradiol (E2)	0 – 1500 pg/mL	Estradiol ID/GC/MS	0, 50, 300, 600, 1650 pg/mL
FSH	0 - 200 mIU/mL	WHO International Standard Follicle Stimulating Hormone (FSH), Human Recombinant, for Immunoassay NIBSC code 92/510	0, 10, 50, 100, 220 mIU/mL

LH	0 – 150 mIU/mL	WHO International Standard Luteinizing Hormone, Human, Pituitary NIBSC code: 80/552	0, 10, 25, 75, 165 mIU/mL
Prolactin (PRL)	0 – 250 ng/mL	WHO 3 rd International Standard Prolactin, Human Pituitary NIBS Code 84/500	0, 20, 75, 150, 275 ng/mL

Stability:

Shelf Life - Stability studies independent of associated reagents were performed for a period of at least 12 months. LOCI 8 Calibrator was stored at -20° C throughout the testing cycle. The studies support the sponsor’s claimed stability of 12 months when stored at -20°C.

Open Vial - Vials are thawed and opened on day zero. A quantity sufficient for a single calibration is withdrawn and the vials are re-capped and stored at 2 - 8°C. The material in these vials is tested on Day 8 versus freshly thawed material. The studies support the sponsor’s claimed stability of 7 days when opened and then stored at 2 to 8°C.

Punctured Vial - Vials are thawed on day zero and the appropriate amount of material is withdrawn leaving sufficient volume for one calibration and the dead volume. All punctured vials are stored at 2 - 8° C with 75% humidity. Two unopened vials and four punctured vials are tested on day 0; four unopened and eight punctured vials are tested on day 8. The recovery of each individual punctured vial is compared to the mean value for the un-opened vials. The studies support the sponsor’s claimed stability of 7 days when the vials are punctured and then stored on board the Dimension Vista® System.

Stress Testing - Stress testing is performed by exposing vials of the product to three elevated temperature profiles during the first week. Stressed samples are tested at several time points and results compared with those from the product that experienced only normal storage.

Acceptance Criteria - The acceptance criterion for each method is expressed in terms of a drift in recovery versus time. Each analyte must meet the pre-determined acceptance criteria for storage conditions recommended by the manufacturer.

d. Detection limit:

Not Applicable

e. Analytical specificity:

Not Applicable

f. Assay cut-off:

Not Applicable

2. Comparison studies:

a. Method comparison with predicate device:

Not Applicable

b. Matrix comparison:

Not Applicable

3. Clinical studies:

a. Clinical Sensitivity:

Not Applicable

b. Clinical specificity:

Not Applicable

c. Other clinical supportive data (when a. and b. are not applicable):

Not Applicable

4. Clinical cut-off:

Not Applicable

5. Expected values/Reference range:

The assigned values are printed in the labeling of the calibrators as follows:

LOCI 8 Calibrator KC646 – Luteinizing Hormone (LH) mIU/mL	
Level	Assigned value
A	0
B	10
C	25

D	75
E	165
LOCI 8 Calibrator KC646 –Follicle Stimulating Hormone (FSH) mIU/mL	
Level	Assigned value
A	0
B	10
C	50
D	100
E	220
LOCI 8 Calibrator KC646 - Prolactin (PRL) ng/mL	
Level	Assigned value
A	0
B	20
C	75
D	150
E	275
LOCI 8 Calibrator KC646 – Estradiol (E2) pg/mL	
Level	Assigned Value
A	0
B	50
C	300
D	600
E	1650

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.